



UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/849,686	08/21/97	DEGGERDAL	A 082697003001

HM12/0512

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EXAMINER

KUNZ, G

ART UNIT	PAPER NUMBER
1623	13

DATE MAILED: 05/12/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12-16-98

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-24 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 1-24 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892  
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

08/849,686

-SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1623

Applicant's request for reconsideration filed 12-16-98 has been received and entered into the record.

Claims 1 - 24 are pending in the case.

All 35 USC statutes not cited in this Office action can be found cited in full in a previous Office action.

The previous rejection of claims 1 - 24 under 35 USC 112, first paragraph, as failing to present the best mode has been withdrawn in view of applicant's persuasive arguments.

### ***35 USC 102 Rejection***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 - 2 are 14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by 1994 Pharmacia Biotechnology Products Catalog.

Claims 1 -2 are directed to a method for isolating nucleic acids generally (claim 1) and RNA specifically (claim 2) by contacting a sample with a detergent and an organic support and then separating out the support with the nucleic acid bound from the impurities. The Pharmacia Catalog discloses oligo(dT) Cellulose (Product Code No. 27-5543-01) for the isolating of mRNA from a cell lysate which can certainly contain any conventional detergent. Oligo(dT) Cellulose is certainly an organic support which can bind mRNA in the presence of detergents. Furthermore,

Art Unit: 1623

the material can be washed and the nucleic acid eluted with heat which simply denatures the double-stranded nucleic acid. This reference fully meets the requirements of claim 14 also.

***35 USC 103 Rejections (New)***

Claims 1 - 12 and 14 - 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the 1994 Pharmacia Biotechnology Products Catalog.

The claims are directed to a method for isolating nucleic acids by binding them to an organic support in the presence of a detergent and other conventional buffers, chelating agents, etc. The support is separated from the impurities and the nucleic acid eluted with heat (claim 14).

The Pharmacia Catalog discloses Oligo(dT) Cellulose which is an organic support which can bind nucleic acids in the presence of a detergent, buffers, salt, and chelating agents, then elute said nucleic acid upon heating. Therefore, the instantly claimed method would have been prima facie obvious in the absence of clear and convincing evidence to the contrary.

Claims 1 - 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reardon et al. (4,997,932).

The claims are directed to a method for isolating RNA or DNA by binding said nucleic acid to an organic support in the presence of a detergent and other conventional cell lysate components (buffers, salts, chelating agents, etc.) and then eluting said nucleic acid by heating.

Reardon et al. teaches the isolation of RNA or DNA by binding said nucleic acid to an organic support (anion exchange resin). See column 2, line 35 - column 3, line 32. In example 1, a cell lysate is added to the anion exchange resin. The lysate contains a TRIS buffer, a chelating

Art Unit: 1623

agent (EDTA), and a detergent (Triton-X). The mode of elution of the nucleic acid from the anion exchange resin is by high salt solutions. However, depending upon the strength of the anion exchange resin and the size of the nucleic acid, heat can also be used to elute the nucleic acid. Therefore, both the method of isolating nucleic acids and a kit containing an organic support and a detergent for performing same would have been obvious to the person of ordinary skill in the art at the time of the invention wanting a convenient and high capacity way to purify nucleic acids from cell lysates and other solutions.

Claims 13 and 19 - 21 have been included within the above obviousness rejection because the way the specification defines "supports" for use in the instant invention, said supports can possess a strong or weak ionic charge. See page 11, second paragraph. Therefore, it would have been obvious to use any standard organic polymer as a support for an anion exchange resin for the purification of nucleic acids taught by Reardon et al.

Claims 13 and 19 - 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Because of the definition of "support" on page 11, second paragraph, of the specification, the specific mention of a polymer organic support renders the claims vague and indefinite. The applicant is requested to clarify for the record precisely what is the scope of claims 13 and 19 - 21 which recite specific polymers. In other words, are these polymers charge neutral or can they possess an anionic functional group?

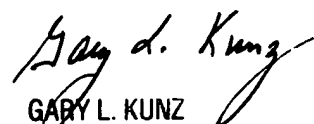
Art Unit: 1623

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kunz, whose telephone number is (703) 308-4623. The examiner can normally be reached on Tuesday through Friday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marion Knode, can be reached on (703) 308-4311. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
GARY L. KUNZ  
PRIMARY EXAMINER  
GROUP 1200